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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,798	10/12/2001	Joseph C. Trautman	ARC 3043 R1	2432

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EXAMINER

THOMPSON, KATHRYN L

ART UNIT PAPER NUMBER

3763

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/976,798

Applicant(s)

TRAUTMAN ET AL.

Examiner

Kathryn L. Thompson

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3,7,8,10,11 and 40-45 is/are pending in the application.
- 4a) Of the above claim(s) 40-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-3,7,8,10 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 July 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

The drawings were received on 07-15-2004. These drawings are not acceptable. The Examiner has not entered the drawings as they appear to be new matter as described below.

### ***Specification***

The amendment filed 07-15-2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amended specification and drawings submitted 07-15-2004 contain new matter giving new data showing depth of penetration and duration in the least.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes et al (WO 98/28037). Theeuwes et al discloses a method of delivering or sampling glucose through the stratum corneum comprising providing a microprotrusion

member having one or more stratum corneum-piercing microprotrusions, forming one or more microslits through the stratum corneum, and delivering or sampling glucose through said microslits (Page 2, Line 34- Page 3, Line 19). Theeuwes does not disclose impacting the stratum corneum with a power of at least 0.05 joules per cm<sup>2</sup> of the microprotrusion member in 10 milliseconds or less. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to impact the stratum corneum with a power of at least 0.05 joules per cm<sup>2</sup> of the microprotrusion member in 10 milliseconds or less because Applicant has not disclosed that this measurement provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the measurement taught by Theeuwes or the claimed measurement. Therefore, it would have been an obvious matter of design choice to modify Theeuwes to obtain the invention as specified in claim 8.

Claims 1-3, 7, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes et al (WO 98/28037), Effenhauser (WO 96/17648), Gerstel et al (US 3,964,482), Gross et al (US 5,279,544), Godshall et al (US 5,879,326). The aforementioned patents all disclose a method of delivering or sampling glucose through the stratum corneum comprising providing a microprotrusion member having one or more stratum corneum-piercing microprotrusions, forming one or more microslits through the stratum corneum, and delivering or sampling glucose through said microslits. However, they do not disclose impacting the stratum corneum with a power

of at least 0.05 joules per cm<sup>2</sup> of the microprotrusion member in 10 milliseconds or less. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to impact the stratum corneum with a power of at least 0.05 joules per cm<sup>2</sup> of the microprotrusion member in 10 milliseconds or less because Applicant has not disclosed that this measurement provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the measurement taught by Theeuwes et al (WO 98/28037), Effenhauser (WO 96/17648), Gerstel et al (US 3,964,482), Gross et al (US 5,279,544), and Godshall et al (US 5,879,326) or the claimed measurement. Therefore, it would have been an obvious matter of design choice to modify Theeuwes et al (WO 98/28037), Effenhauser (WO 96/17648), Gerstel et al (US 3,964,482), Gross et al (US 5,279,544), and Godshall et al (US 5,879,326) to obtain the invention as specified in claims 1-3, 7, 10, and 11.

### ***Response to Arguments***

Applicant's arguments filed 07-15-2004 have been fully considered but they are not persuasive. Applicant states that Examiner's 103(a) design choice rejection is improper. Examiner respectfully disagrees. Applicant does not provide in his disclosure any reason as to why he choose the exact number of 0.05 joules per square centimeter in 10 milliseconds or less. That is, why that number is any different or better than any other number. Thus, Examiner maintains her 103(a) design choice rejection.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn L. Thompson whose telephone number is 703-305-3286. The examiner can normally be reached on 8:30 AM - 6:00 PM: 1st Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 703-308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KLT



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